Summary of Health Data for

SUMMARY

The test substance has a low order of toxicity via the dermal and inhalation routes of exposure, and is moderately toxic via the oral route of exposure (LD50 = 653 mg/kg). The test substance elicited very slight irritation when applied to the skin of rabbits, but was severely irritating to the eyes of rabbits. In a guinea pig maximization test, the test substance was considered a moderate skin sensitizer. The test substance did not induce gene mutation, with or without metabolic activation.

TOXICOLOGY DATA

Acute Toxicity

Oral. An acute oral study was designed to determine the LD50 of the test substance in the Sprague-Dawley rats. The procedure followed was in accordance with the acute oral toxicity studies specified in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," published in December, 1979. Four dose levels, 250, 500, 1000 and 1600 mg/kg of the test substance were administered to ten rats (5/sex) by oral intubation. The oral LD50 of test substance in the rat was 653 (447-892) mg/kg body weight. Signs of toxicity exhibited by rats included extreme lethargy, ataxia, convulsions, and coma. Necropsy of the rats that died during the study showed hemorrhagic conditions of the gastrointestinal tract. Terminal sacrifice of surviving animals did not reveal any compound related gross pathological alteration in the tissues and organs examined (1).

Dermal. An acute dermal toxicity study was designed to determine the dermal LD50 or to establish a non-lethal dose level of 2000 mg of the test substance in albino rabbits. The procedure followed the requirements outlined in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," published in December, 1979. A single dose of 2000 mg/kg body weight was applied to the intact skin of ten rabbits (5/sex). No deaths or behavioral changes and no obvious effects on body weight gains or food consumption were noted during the 14-day observation period. Terminal sacrifice of animals did not reveal any compound related gross pathological alterations in the tissues and organs examined. Under the conditions of this study, it is concluded that the test substance is non-toxic when applied on an acute basis to the intact skin of rabbits and a single dose of the material at a level of 2000 mg/kg body weight is considered a non-lethal dose according to O.E.C.D. definition (2).

Inhalation. An acute inhalation study was conducted with the test substance according to the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981. Male and female Sprague-Dawley rats were exposed to 0 and an average vapor concentration of 0.600 mg/L (nominal concentration) of the test substance for four hours. No deaths and no obvious effects on body weight gains were noted either in the control or exposed animals during the 14-day study period. No abnormal behavior was seen in any of the animals during the exposure or observation periods. There were no apparent abnormalities of major organs and tissues observed at the time of necropsy. These results suggest that the test substance does not pose a significant acute inhalation health hazard (3).

Irritation/Corrosion

Skin. An acute dermal irritation study was designed to determine the skin irritation potential of the test substance when applied to the skin of rabbits. The procedure followed the requirements outlined in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," published in December, 1979. A single semi-occlusive contact of 0.5 ml of the test substance with the intact skin of six male albino rabbits for four hours resulted in slight redness in all animals and slight swelling in one of the rabbits when examined at 60 minutes after washing. Twenty-four hours after treatment, four rabbits continued to show slight skin redness. There was no perceptible skin reaction observed in any of the rabbits after 96 hours. On the basis of the data presented in this report, it is concluded that exposure to 0.5 ml of the test substance may result in very slight irritation to the skin of rabbits (4).

Eye. An acute study was designed to evaluate the eye irritation potential of the test substance in New Zealand White Rabbits. The procedure followed the requirements outlined in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report" published in December, 1979. A single instillation of (0.1 ml) of undiluted the test substance in the eyes of rabbits followed by washing resulted in severe pain, severe conjunctival redness and swelling and corneal opacity persisting for several days. Other signs of irritation observed were eye discharge, congestion of the iris, and slight pannus. Three out of six rabbits continued to exhibit slight corneal injury at 21 days. According to O.E.C.D. definition and under the conditions of this test, the test substance is severely irritating to the eyes of rabbits and therefore a direct eye contact with this material may result in permanent eye damage (5).

Skin Sensitization

Guinea Pig Maximization Test. A screening test was designed to determine the delayed contact hypersensitivity potential of the test substance in guinea pigs. The procedure used to evaluate this material was the Guinea Pig Maximization Test of Magnusson and Kligman (1969). Two groups of guinea pigs, one experimental, and one vehicle control (20 animals/group) were used in this study. Forty-five percent of the animals exhibited a sensitization response to the test

substance. No evidence of skin irritation or skin sensitization was observed in any of the animals of the control group. Under the conditions of this study, the test substance is considered to have a moderate potential to produce skin sensitization in guinea pigs (6).

Genetic Toxicity

In vitro Gene Mutation. The test substance was evaluated for genetic activity in the Salmonella typhimurium and Escherichia coli Reverse Mutation. The test was performed with five strains of Salmonella typhimurium (TA98, TA100, TA1535 and TA1537) and Escherichia coli (WP2) with and without metabolic activation. The direct plate incorporation method was used, and conducted in triplicate. It was concluded from the results that under the conditions of this study, the test substance did not induce gene mutation, with or without metabolic activation (7).

REFERENCES

1. Internal Report:
2. Internal Report:
3. Internal Report:
4. Internal Report:
5. Internal Report:
6. Internal Report:
7. Internal Report:

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